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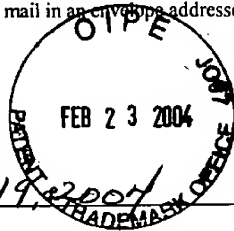
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

PATENT  
Attorney Docket No.: 015280-310100US  
Client Reference No.: E-057-97/1

On FEBRUARY 19, 2004

TOWNSEND and TOWNSEND and CREW LLP

By: Humberto Roca



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**FEB 27 2004**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

FITZGERALD, David J.

Application No.: 09/462,682

Filed: April 28, 2000

For: *PSEUDOMONAS* EXOTOXIN  
A-LIKE CHIMERIC IMMUNOGENS

Examiner: Portner, Virginia Allen

Art Unit: 1645

SUPPLEMENTAL INFORMATION  
DISCLOSURE STATEMENT UNDER 37  
CFR §1.97 and §1.98

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

The references cited on attached form PTO/SB/08A and PTO/SB/08B are being called to the attention of the Examiner. Copies of the reference Nos. 1-39 are enclosed. Copy of reference No. 0 is not enclosed, since it is a continuation application of USSN 09/462,713 whose specification has been previously disclosed.

It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

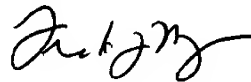
As provided for by 37 CFR 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no

representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

This IDS is being filed before the mailing date of the final Office Action or Notice of Allowance.

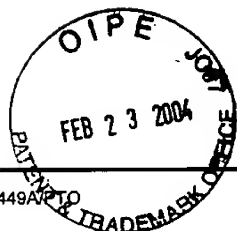
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Respectfully submitted,



Frank J. Mycroft  
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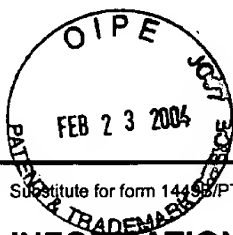
<b>Substitute for form 1449A</b> <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		<b>Complete if Known</b> <b>RECEIVED</b>	
		Application Number	09/462,682
		Filing Date	April 28, 2000
		First Named Inventor	FitzGerald, David
		Art Unit	1645
Examiner Name	Portner, Virginia Allen		
Attorney Docket Number	015280-310100US		
Sheet	1	of	3

U.S. PATENT DOCUMENTS+					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	0	US-10/659,036	n/a	Fitzgerald et al.	
	1	US-4,545,985	10-08-1985	Pastan et al.	
	2	US-5,573,916	11-12-1996	Cheronis et al.	
	3	US-5,821,238	10-13-1998	Pastan et al.	
	4	US-5,869,045	02-09-1999	Hellstrom et al.	
	5	US-5,980,896	11-09-1999	Hellstrom et al.	
	6	US-6,011,002	01-04-2000	Pastan et al.	
	7	US-6,020,145	02-01-2000	Hellstrom et al.	
	8	US-6,051,405	04-18-2000	Fitzgerald et al.	
	9	US-6,099,842	08-08-2000	Pastan et al.	
	10	US-6,140,066	10-31-2000	Lorberboum-Galski et al.	
	11	US-6,423,513 B1	06-23-2002	Fitzgerald et al.	
	12	US-6,426,075 B1	06-30-2002	Fitzgerald et al.	
	13	US-6,531,133 B1	03-11-2003	Lorberboum-Galski et al.	

FOREIGN PATENT DOCUMENTS								
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		Application Number	09/462,682
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		Filing Date	April 28, 2000
		First Named Inventor	FitzGerald, David
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Sheet	2	of	3

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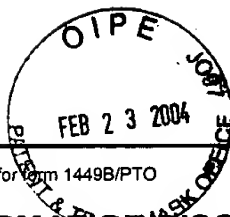
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NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	14	BATRA, J.K. et al.: "Single-chain immunotoxins directed at the human transferring receptor containing <i>Pseudomonas</i> exotoxin A or diphtheria toxin: anti-TFR(Fv)-PE40 and DT388-anti-TFR(Fv)" <i>Mol. Cell. Biol.</i> ; Vol. 11, No. 4; pp. 2200-2205 (Apr. 1991)	Abstr. only
	15	BERAUD, E. et al.: "Immunospecific suppression of encephalitogenic-activated T lymphocytes by chimeric cytotoxin IL-2-PE40" <i>Cell. Immunol.</i> ; Vol. 133, No. 2; pp. 379-389 (Apr. 1991)	Abstr. only
	16	CHOE, M. et al.: "B3(Fab)-PE38M: a recombinant immunotoxin in which a mutant form of <i>Pseudomonas</i> exotoxin is fused to the Fab fragment of monoclonal antibody B3" <i>Cancer Res.</i> ; Vol. 54, No. 13; pp. 3460-3467 (Jul. 1994)	Abstr. only
	17	DEBINSKI, W. and I. PASTAN: "Recombinant F(ab') <sub>2</sub> C242- <i>Pseudomonas</i> exotoxin, but not the whole antibody-based immunotoxin, causes regression of a colorectal tumor xenograft" <i>Clin. Cancer Res.</i> ; Vol. 1; pp. 1015-1022 (Sept. 1995)	
	18	GAWLAK, S.L. et al.: "Basic fibroblast growth factor- <i>Pseudomonas</i> exotoxin chimeric proteins; comparison with acidic fibroblast growth factor- <i>Pseudomonas</i> exotoxin" <i>Bioconjug. Chem.</i> ; Vol. 4, No. 6; pp. 483-489	Abstr. only
	19	GORSE, G.J. et al.: "Salivary binding antibodies induced by human immunodeficiency virus type 1 recombinant gp120 vaccine" <i>Clinical and Diagnostic Laboratory Immunology</i> ; Vol. 3, No. 6; pp. 769-773 (1996)	
	20	HELMBROOK, D.C. et al.: "Transforming growth factor alpha- <i>Pseudomonas</i> exotoxin fusion protein prolongs survival of nude mice bearing tumor xenografts" <i>Proc. Natl. Acad. Sci. USA</i> ; Vol. 87, No. 12; pp. 4697-4701 (Jun. 1990)	Abstr. only
	21	JOHANSEN, H. K. "Potential of preventing <i>Pseudomonas aeruginosa</i> lung infections in cystic fibrosis patients: experimental studies in animals" <i>APMIS Suppl.</i> ; No. 63, Vol. 104; pp. 5-42 (1996)	
	22	JOHANSEN, H. K. et al.: "Clearance of <i>Pseudomonas aeruginosa</i> from normal rat lungs after immunization with somatic antigens or toxin A" <i>APMIS</i> ; No. 102; pp. 545-553 (1994)	
	23	KREITMAN, R.J. et al.: "Properties of chimeric toxins with two recognition domains: interleukin 6 and transforming growth factor alpha at different locations in <i>Pseudomonas</i> exotoxin" <i>Bioconjug. Chem.</i> ; Vol. 3, No. 1; pp. 63-68	Abstr. only
	24	KREITMAN, R.J. and I. PASTAN: "Purification and characterization of IL6-PE4E, a recombinant fusion of interleukin 6 with <i>Pseudomonas</i> exotoxin" <i>Bioconjug. Chem.</i> ; Vol. 4, No. 6; pp. 581-585	Abstr. only
	25	KUAN, C.T. and I. PASTAN: "Improved antitumor activity of a recombinant anti-Lewis immunotoxin not requiring proteolytic activation" <i>Proc. Natl. Acad. Sci. USA</i> ; Vol. 93; pp. 974-978 (Feb. 1996)	
	26	KUAN, C.T. et al.: "Immunotoxins containing <i>Pseudomonas</i> exotoxin that target LeY damage human endothelial cells in an antibody-specific mode: relevance to vascular leak syndrome" <i>Clin. Cancer Res.</i> ; Vol. 1, No. 12; pp. 1589-1594 (Dec. 1995)	Abstr. only
	27	KUAN, C.T. et al.: " <i>Pseudomonas</i> exotoxin A mutants. Replacement of surface exposed residues in domain II with cysteine residues that can be modified with polyethylene glycol in a site-specific manner" <i>J. Biol. Chem.</i> ; Vol. 269, No. 10; pp. 7610-7616 (Mar. 1994)	Abstr. only
	28	LEGER, O.J.P. et al.: "Humanization of a mouse antibody against alpha-4 integrin: a potential therapeutic for the treatment of multiple sclerosis" <i>Human Antibodies</i> ; Vol. 8; No. 1; pp. 3-16 (1997)	
	29	MANSFIELD, E. et al.: "Characterization of RFB4- <i>Pseudomonas</i> exotoxin A immunotoxins targeted to CD22 on B-cell malignancies" <i>Bioconjug. Chem.</i> ; Vol. 7, No. 5; pp. 557-563	Abstr. only

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet **3** of **3****Complete if Known**

Application Number	09/462,682
Filing Date	April 28, 2000
First Named Inventor	FitzGerald, David
Art Unit	1645
Examiner Name	Portner, Virginia Allen
Attorney Docket Number	015280-310100US

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**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	30	MICKISCH, G.H. et al.: "Pseudomonas exotoxin conjugated to monoclonal antibody MRK16 specifically kills multidrug resistant cells in cultured renal carcinomas and in MDR-transgenic mouse" <u>J. Urol.</u> ; Vol. 149, No. 1; pp. 174-178 (Jan. 1993)	Abstr. only
	31	PAI, L.H. et al.: "Antitumor activity of a transforming growth factor alpha-Pseudomonas exotoxin fusion protein (TGF-alpha-PE40)" <u>Cancer Res.</u> ; Vol. 51, No. 11; pp. 2808-2812 (Jun. 1991)	Abstr. only
	32	PAI, L.H. et al.: "Treatment of advanced solid tumors with immunotoxin LMB-1: an antibody linked to Pseudomonas exotoxin" <u>Nat. Med.</u> ; Vol. 2, No. 3; pp. 350-353 (Mar. 1996)	Abstr. only
	33	PARR, E.L. and M. B. PARR: "Immunoglobulin G is the main protective antibody in mouse vaginal secretions after vaginal immunization with attenuated HSV-2." <u>J. Virol.</u> ; pp. 8109-8115 (1997)	
	34	PURI, R.K. et al.: "A chimeric protein comprised of IL-4 and Pseudomonas exotoxin is cytotoxic for activated human lymphocytes" <u>J. Immunol.</u> ; Vol. 152, No. 7; pp. 3693-3700 (Apr. 1994)	Abstr. only
	35	REITER, Y et al.: "Cytotoxic and antitumor activity of a recombinant immunotoxin composed of disulfide-stabilized anti-Tac Fv fragment and truncated Pseudomonas exotoxin" <u>Int. J. Cancer</u> ; Vol. 58, No. 1; pp. 142-149 (Jul. 1994)	Abstr. only
	36	SIEGALL, C.B. et al.: "In vivo activities of acidic fibroblast growth factor-Pseudomonas exotoxin fusion proteins" <u>Bioconjug. Chem.</u> ; Vol. 5, No. 1; pp. 77-83	Abstr. only
	37	THEUER, C. et al.: "Domain II of Pseudomonas exotoxin A arrests the transfer of translocating nascent chains into mammalian microsomes" <u>Biochemistry</u> ; Vol. 33, No. 19; pp. 5894-5900 (May 1994)	Abstr. only
	38	THEUER, C.P. et al.: "Immunotoxins made with a recombinant form of Pseudomonas exotoxin A that do not require proteolysis for activity" <u>Cancer Res.</u> ; Vol. 53, No. 2; pp. 340-347 (Jan. 1993)	Abstr. only
	39	THEUER, C.P. et al.: "The N-terminal region of the 37-kDa translocated fragment of Pseudomonas exotoxin A aborts translocation by promoting its own export after microsomal membrane insertion" <u>Proc. Acad. Natl. Sci. USA</u> ; Vol. 90, No. 16; pp. 7774-7778 (Aug. 1993)	Abstr. only

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